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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,820	01/05/2004	Douglas S. McNair	CRNC.103792	3634
46169 7590 01/10/2007 SHOOK, HARDY & BACON L.L.P. Intellectual Property Department 2555 GRAND BOULEVARD KANSAS CITY, MO 64108-2613			EXAMINER NGUYEN, TRAN N	
			ART UNIT	PAPER NUMBER
			2197	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/751,820

Applicant(s)

MCNAIR, DOUGLAS S.

Examiner

Tran N. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06/07/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In pursuant to 37 CFR 1.33(a), Examiner respectfully requests Applicant to update the daytime telephone number of the party to whom correspondence is to be addressed. This is necessary to facilitate compact prosecution of the instant pending application.

Examiner respectfully directs Applicant's attention to the fact that all applications must comply with all applicable requirements set forth in 35 U.S.C. and 37 C.F.R., as well as all applicable guidelines set forth in the MPEP. Applicant's attention is also directed to instances where terminology, language, grammar, and other informalities may render the interpretation ambiguous, or otherwise introduce errors into the instant pending application. Even if the claims were amended to an allowable state, these issues may prevent early and favorable consideration for Applicant. Therefore, Examiner respectfully suggests and strongly urges Applicant to consider the instant pending application in view of the issues raised henceforth.

Additionally, Examiner respectfully requests Applicant to continue to number all lines in the disclosure, including claims, specification, and abstract. This will facilitate the examination process and will result in compact prosecution for Applicant.

Priority

Examiner hereby acknowledges Applicant's claim of priority to US Application 60/446,692, filed on 02/11/2003; however, Examiner respectfully cautions Applicant in regards to any future amendment that may introduce new matter that has no support in the application(s) to which Applicant claims priority. Furthermore, the aforementioned application appears to lack in-depth analysis as to fully provide support for the claimed subject matter in the instant pending application; however, Examiner has adopted a broad interpretation of the application(s) to which Applicant claims priority and hereby provisionally grants the claimed priority date to all pending claims in the instant pending application. It should be noted that, however, should an intervening reference be discovered as the result of Applicant's amendment, Applicant's claim to priority would be more closely scrutinized for subject matter for which no support exists in the application(s) to which Applicant claims priority.

Response to Amendment

Applicant's amendment to the drawings filed 06/07/2004 is hereby acknowledged and entered. Applicant is thanked for the clear and legible formal drawings.

Specification

The listing of references in the specification (page 21) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states,

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"the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The disclosure is objected to because of the following informalities:

- Applicant states "[o]nly two variables are required, one from each of the two following categories." (page 6, paragraph 0017). It is unclear from Applicant's disclosure if only two variables are required for each locale, one from each category, or if only one variable is required for each locale, and the variable may be derived from either category.
- The following equation is incorrect (page 7):

$$\text{sign}(\lambda_j) = \begin{cases} +1 & \text{if } \geq 0 \\ -1 & \text{otherwise} \end{cases}$$

Applicant has failed to disclose the parameter on which the quantifier "if ≥ 0 " is acting, i.e. it is not clear if Applicant is disclosing $\lambda_j \geq 0$ or $j \geq 0$.

- The following equation appears to contain errors, especially with regards to t and s . Applicant is also respectfully requested to examine all proceeding instances of $E()$.

$$E(\epsilon_{jt}, \epsilon_{jt}) = \Omega_{jt} \text{ and } E(\epsilon_{jt}, \epsilon_{js}) = 0 \text{ for } t \neq s$$

Additional errors may exist in the disclosure. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is replete with errors. The following is a non-exhaustive list of errors present in claim 1.

Claim 1 recites the limitation "a county or local level" (line 2). This limitation is indefinite because one of ordinary skill in the art considers a county to be local government. Examiner appreciates the fact that the set of local government may be comprised of a county, but the set of local government may be comprised of city, towns, and other municipalities as well. Because one of ordinary skill in the art normally regards the limitation "local level" to envelop county government, it is unclear why Applicant recited the limitation "county". Therefore, this limitation is indefinite because Applicant has not provided a definition of what Applicant considers to be the local level.

Applicant further states: "[t]he distance index and model of the present invention can be used for econometrics and clinical process consulting work with health care organizations in various countries and in various regions within any country, irrespective of the locale's rurality and regardless of how much of the health care provided by institutions in that locale is delivered to persons whose episodes of care originated

outside the nominal catchment area for that locale's health jurisdiction" (page 5, paragraph 0014).

For examination purposes, Examiner considers this limitation intended use, and therefore this limitation does not limit the scope of the claim because the recited method steps do not breath life into this limitation as recited by the preamble.

Claim 1 further recites the limitation "said proband counts" in line 6. There is insufficient antecedent basis for this limitation in the claim. No proband counts have been previously introduced in the scope of claim 1. Applicant recited "transmissions data" (line 4); however, it is unclear if transmissions data constitute proband counts.

Claim 1 further recites the limitation "distance values" in line 7. There is insufficient antecedent basis for this limitation in the claim. No distance values have been previously introduced in the scope of claim 1. It is unclear if the transmissions data discussed above constitute distance values.

Claim 1 further recites the limitations "miles (kilometers)" (line 7) and "square mile (square kilometer)" (lines 11-12). It is unclear from Applicant's recitation if Applicant intends for the measurements to be in metric or Imperial units.

For examination purposes, Examiner interprets these limitations to recite that distance may be measured in either metric or Imperial units.

Claim 1 further recites the limitation "the catchment area" in line 9. There is insufficient antecedent basis for this limitation in the claim. No catchment area has been previously introduced in the scope of claim 1. Furthermore, it is indefinite whether the recited catchment area belongs to the "a health facility" (line 9) or the "a plurality of corresponding institutions" (line 5).

For examination purposes, Examiner interprets this limitation to refer to the catchment area served by the health care facility recited in line 9.

Claim 1 further recites the limitation "power transform" (line 9). Because Applicant did not claim any particular power transformation method, this limitation is indefinite because the list of known methods of power transformation may change as time progresses and new methods are discovered. Therefore, it is unclear which method Applicant intends to employ.

Claim 1 further recites the limitations " λ_1 " and " λ_2 " (page 26, lines 1-2 and 4). These limitations are indefinite because not all power transformations use these parameters to normalize the observed values. Furthermore, Applicant recites the Box-Cox power transformation (page 7, paragraphs 0019). It is unclear if Applicant intends to recite the Box-Cox transformation, or if the limitations " λ_1 " and " λ_2 " are meant to apply to any power transformation method.

For examination purposes, Examiner interprets this limitation to recite the Box-Cox power transformation.

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Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “dcat” in claim 1 is used by the claim to mean “a value derived from transformed distance between the origin location of the episode and the care service venue where the episode was consummated, or from which resources were dispatched in the case of patients treated in situ” (paragraph 0026), while the accepted meaning does not exist because “dcat” is not a word. The term is indefinite because neither the claim or the specification clearly defines the term.

To overcome this rejection, Examiner suggests Applicant to clearly recite the definition of “dcat” in the claim as to reasonable apprise one of ordinary skill in the art of the scope of the claim.

Claim 1 further recites the limitation “optionally, other variables” (line 10). Although Applicant may use the term “optionally” to recite claim limitations, the alternatives must be clear (MPEP 2173.05(h)). This limitation is indefinite because the list of potential alternatives can vary.

Claim 1 further recites the limitation “so as to produce an **accurate** representation” (line 12). This limitation is indefinite because Applicant has failed to

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define in the specification what Applicant regards as the measurement of accuracy. Specifically, Applicant has failed to disclose what Applicant regards as statistically significant or insignificant, i.e. confidence intervals, and hence a measure of accuracy has not been provided by Applicant.

As discussed above, claim 1 is replete with errors. Due to the highly technical nature of the subject matter, Examiner requires Applicant to clearly and positively recite all limitations of the claimed invention, including any and all equations and all parameters, including explicit definitions and any additional limitations, thereof.

Although Applicant provides exemplary embodiments in the disclosure, it is not proper for Examiner to import limitations from the specification into the claim if those limitations were not explicitly recited by the claim. Therefore, Applicant is respectfully requested and strongly urged to review the application in its entirety in view of these issues.

Specifically, Examiner strongly urges Applicant to compare and contrast the various definitions of the recited terms as intended by Applicant with those generally accepted in the art. Where there exists discrepancies, Applicant should clearly address these differences as to reasonably apprise one of ordinary skill in the art of the metes and bounds of the claim. See MPEP 702.01.

For examination purposes, Examiner interprets claim 1 to recite collecting distance data, normalizing said data using the Box-Cox transformation, iteratively deducing the optimal parameters of the Box-Cox power parameters to minimize the

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Anderson-Darling measure of deviation from normality, and risk-adjusting based on the transformed data.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

With respect to claim 1, claim 1 recites subject matter that does not have a platform or otherwise lacks structural limitations. Furthermore, the claimed subject matter does not produce a physical transformation because the steps involved are mere mathematical algorithm. The result of such algorithm constitutes mathematical transformation per se, and no physical transformation has been provided.

Furthermore, the recited steps may be performed in the mind of a person. Additionally, the recited steps may be performed by human beings themselves with pen and paper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over article

Geographic Variations in Utilization Rates in Veterans Affairs Hospitals and Clinics

(1999) by Ashton et al. (hereafter referred to as Ashton) in view of Horn

(2003/0018633). Both references are from the same field of health care management, and both references address the same problem of calculating intervals for skewed data samples containing outliers.

With respect to claim 1, Ashton teaches accessing a database containing clinical data obtained from the Veterans Health Administration (VHA) of the Department of Veterans Affairs (VA) to examine the health care utilization pattern of veterans (page 32, column 1, Methods). This database contains data obtained from the VHA's 22 Veterans Integrated Services Networks (VISNs) of geographically based network of VHA hospitals, clinics, and other health providers.

Ashton further teaches a method that “adjusted within each cohort for differences in physiologic reserve, measures of social support (based on age, sex, race, and marital status), and the type and complexity of the patients’ conditions” (page 34, column 1). According to Ashton’s teachings, “[w]e used covariates related to the defining discharge to adjust the risk at the time a patient was enrolled, and we updated risk profiles after each 24 months in the study, using data from the most recent hospitalization” (page 34, column 1).

Ashton further teaches “[a]nalysis of covariance was used to adjust for the patients’ characteristics and to estimate the means of the utilization measures according to the network for each year. The patients’ characteristics were the demographic and clinical variables described above plus the fiscal year of entry into the cohort. The unit of analysis was the individual patient. The models were tested for interaction between the networks and the patients’ characteristics. The average use of services per person was transformed to the average use of services per person-year at each network. The ranks of the networks were based on the average rates of use per network per year” (page 34, column 1).

With regards to statistical modeling, Ashton teaches that “Pearson, Spearman, and intraclass correlations were used in the analysis” (page 34, columns 1-2).

According to the teachings of Ashton, patient utilization of health care services is calculated using intraclass correlations (page 34, column 2).

Ashton does not teach the normalizing of data using the Box-Cox distribution; however, Horn teaches the use of the Box-Cox method of power transformation to remove skew, or lack of normality, from a set of data samples (pages 4-5, paragraphs 0030-0052).

Ashton also does not teach the use of the Anderson-Darling measure of deviation from normality to determine the optimal value of λ_1 and λ_2 ; however, Applicant has admitted that "[r]isk-adjustment of indicator incidence rates may follow any of the methods known to those experienced in the art. The risk-adjustment must then be validated according to accepted statistical practices before... the optimized values for λ_1 and λ_2 are deployed" (page 8).

Therefore, based upon Horn's teachings and Applicant's admission, and absent any evidence of criticality, it is obvious to one of ordinary skill in the art to use the Box-Cox power transformation to normalize skewed data, and to apply any accepted statistical practice (e.g. R-squared error sampling as taught by Ashton, page 34, column 1; exploratory data analysis for cutoffs as taught by Horn, Figure 2) to validate the optimized values of λ_1 and λ_2 when calculating the utilization profile, as taught by Ashton, without any unexpected results.

The skilled artisan would have been motivated by Horn's teachings that "a significant need exists for a Reference Interval estimator that will provide a reliable Reference Interval based on a small sample set" (page 2, paragraph 0014). Therefore, by implementing the Box-Cox power transformation as taught by Horn, the skilled

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artisan would have realized the benefit of deriving a normally distributed sample from a small sample size that is more prone to skewing.

Furthermore, the skilled artisan would have also been motivated by the need to verify and minimize the error of the Box-Cox transformation, such as by way of computing the upper robust reference interval and 90% confidence intervals as taught by Horn (Figure 2). Therefore, the skilled artisan would have realized the benefit of verifying the goodness-of-fit before committing to the values obtained from the Box-Cox transformation.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following reference(s) are cited but not applied:

1. Article *Hospital Use and Survival among Veterans Affairs Beneficiaries* (2003) by Ashton et al. (hereafter referred to as Ashton '03). Ashton '03 further teaches the use of the use of a nonhierarchical Cox regression model and random-coefficient linear regression (pages 1641-1642).
2. Article *Understanding Geographic Variations in Health Care Delivery* (1999) by Wennberg. Wennberg further discusses the significance of the method presented by Ashton.
3. Seare (5,557,514) teaches a method of generating health care utilization profiles based on a plurality of statistics.

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Any inquiry concerning this communication or earlier communications from Examiner should be directed to Tran N. Nguyen (Ken) whose telephone number is (571) 270 - 1310. Examiner may normally be reached on Monday - Friday, 7:30 am - 5:00 pm, Eastern Time. Applicant is hereby advised that Examiner is on a compressed work schedule that allows him to be off-duty every other Friday.

If attempts to reach Examiner by telephone are unsuccessful, Examiner's Supervisor, Gary Jackson may be reached on (571) 274 - 1279. The fax phone number for the organization where this application or proceeding is assigned is (571) 273 - 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217 - 9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call (800) 786 - 9199 (in USA or Canada) or (571) 272 - 1000.

Tran N Nguyen
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Art Unit 2197

TN
1/2/2007


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PRIMARY EXAMINER